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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/967,321	10/01/2001	Jonathon Michael Blackburn	0623.0860002/LBB/Y-W	4288

35437 7590 12/18/2008

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
12/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/967,321	BLACKBURN ET AL.	
	Examiner	Art Unit	
	ANN Y. LAM	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,8-14 and 18-27* is/are pending in the application.

4a) Of the above claim(s) *8-12, 14, 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,13,18-24,26 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-4, 13, 18-23, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morin et al., 6,610,839, in view of Chin et al., 6,197,599.

Morin et al. discloses the invention substantially as claimed. As to claim 1, Morin discloses a method comprising

(a) inserting a marker DNA sequence in frame immediately preceding a stop codon of each of a plurality of target DNA sequences to form a plurality of modified DNA sequences which encode a plurality of modified amino acid sequence each comprising a marker moiety (col. 156, lines 20-25) (it is understood that a plurality of modified DNA sequences are encoded, see for example col. 155, lines 29-30, disclosing producing of large quantities of hTRT using *Picha pastoris* expression vector pPICZ B, and col. 156, lines 16-18, disclosing a second *Picha pastoris* expression vector derived from pPICZ B);

(b) expressing the plurality of modified amino acid sequences from the plurality of modified DNA sequences (col. 156, lines 25-29);

(c) purifying and immobilizing each of the plurality of modified amino acid sequences into contact with a solid support wherein the marker moiety of the plurality of modified amino acid sequences is directly attached to the solid support (col. 43, lines 27-34), disclosing the isolation of the proteins by binding the $(HIS)_6$ to resins containing nickel ions, i.e., metal-chelate affinity chromatography, which is a direct attachment to the solid support, as is also disclosed by Applicants' specification) (the isolation step disclosed by Morin et al. is both the step of immobilizing and purifying in a single step, as is also disclosed by Applicants' specification), and

(d) washing said solid support to remove unbound proteins (col. 43, lines 30-34).

Moreover, while Morin et al. teaches use of the fusion protein system to isolate specific proteins and peptides (col. 43, lines 27-29), Morin et al. however does not teach that the bound proteins are in an array. This limitation is taught by Chin et al.

Chin et al. teaches that proteins immobilized on a solid support can be immobilized in an array, or specific position, so it can be identified by its position and further characterized thereby allowing for study of a wide variety of proteins in a single experiment by a large number of proteins on a support (col. 2, line 60 – col. 3, line 3.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the immobilized proteins in the Morin et al. invention in the form of an array as taught by Chin et al. for the advantage of identifying a protein based on its position and studying a wide variety of proteins in a single experiment for convenience.

In combining the teachings of Morin et al. and Chin et al., the skilled artisan would have recognized that the variety of different proteins which can be immobilized on the same support for convenience of identification of a large number of proteins on a single support, as suggested by Chin et al., can be expressed by a library of non-identical DNA sequences and isolated using the tagging method disclosed by Morin et al. as discussed above. Moreover, the skilled artisan would have recognized that the single step of immobilizing (which is also the purification step) disclosed Morin et al. can be performed in an array format, as suggested by Chin et al. for subsequent analysis. That is, the skilled artisan would have recognized that the step of immobilizing can provide for the purification (as taught by Morin et al.) as well as the fabrication of the array for analysis purposes (as taught by Chin et al.), and thus that only one immobilization step in an array format (by printing for example, as disclosed by Chin et al.; col. 5, line 66) would accomplish both purposes, as would be desirable for convenience.

As to the following claims, Morin et al. discloses the limitations as follows.

As to claim 2, the tag is a peptide sequence (col. 156, line 22).

As to claim 3, the tag allows for purification of the individual proteins in the array (col. 43, lines 27-29).

As to claim 4, the tag is inserted such that the start or stop codon for each of the proteins is replaced (column 156, lines 22-23).

As to claims 13 and 26, the array is used to immobilize specific antibodies (col. 43, lines 34-35).

As to claim 18, the protein array comprises kinases (col. 26, line 26.)

As to claim 19, the plurality of modified amino acid sequences are modified human amino acid sequences (see abstract, "human telomerase reverse transcriptase").

As to claim 20, Morin et al. teaches a FLAG marker moiety (col. 153, line 54.)

As to claims 21-23, the marker moiety is post-translationally modified (col. 49, line 44), such as addition of a lipid (col. 49, line 43), and the modified amino acid sequences are folded into the correct formation (col. 49, line 45.)

As to claim 27, Morin et al. teach using nickel ionon for metal-chelate affinity chromatography to bind polyhistidine tracts $(HIS)_6$.

2. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morin et al., 6,610,839, in view of Chin et al, 6,197,599, and further in view of Orr et al., 5,741,645, and Nielsen et al., 6,350,853.

Morin et al. in view of Chin et al. disclose the invention substantially as claimed (see above), except for two markers, one immediately following a start codon and one immediately preceding a stop codon. Orr et al. discloses this limitation.

Orr et al. teaches the use of two flanking markers for the advantage of isolating region-specific DNA markers (col. 16, lines 40-44.) Moreover, Nielsen et al. teaches a marker sequence immediately following a start codon (col. 33, lines 23-26.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide two flanking markers as taught by Orr et al. in the Morin et al. method

because Orr et al. teaches that it provides the advantage of isolating region-specific DNA markers, and it would have been obvious to one of ordinary skill in the art to provide the second marker immediately following a start codon as taught by Nielsen et al. as a known location for inserting a marker. Also, Applicant has not disclosed a use for inserting a marker immediate to the start codon that is a different use from that shown in the prior art.

Response to Arguments

Applicant's arguments have been considered but are not persuasive.

Applicant argues that the purification and immobilization as described by Morin is not to a single support but to variety of supports within the same resin. Applicant further argues that Chin does not remedy the deficiencies of Morin and that Chin relates to construction of an array of biomolecules on a single solid support which requires that each individual member of the array be purified and immobilized separately. Applicant asserts that a reason why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art is lacking. It is thus argued by Applicant that Morin and Chin, considered alone or in combination, do not describe a method of making a protein array by tagging a library of two or more target DNA sequences, and subsequently purifying and immobilizing the tagged expression products directly to a single solid support via the tag moiety, in a single step and in a spatially defined format.

As noted in the grounds for rejection, in combining the teachings of Morin et al. and Chin et al., the skilled artisan would have recognized that the variety of different proteins which can be immobilized on the same support for convenience of identification of a large number of proteins on a single support, as suggested by Chin et al., can be expressed by a library of non-identical DNA sequences and isolated by the tagged method disclosed by Morin et al. Moreover, the skilled artisan would have recognized that the single step of immobilizing (which is also the purification step) disclosed Morin et al. can be performed in an array format, as suggested by Chin et al. for subsequent analysis. That is, the skilled artisan would have recognized that the step of immobilizing can provide for the purification (as taught by Morin et al.) as well as the fabrication of the array for analysis purposes (as taught by Chin et al.), and thus that only one immobilization step in an array format (by printing for example, as disclosed by Chin et al., col. 5, line 66) would accomplish both purposes, as would be desirable for convenience.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN Y. LAM whose telephone number is (571)272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ann Y. Lam/
Primary Examiner, Art Unit 1641